K132934
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APR 10 2014

510(k) Summary: Multix Select DR X-ray System

Company: Siemens Medical Systems, Inc.
1 Valley Stream Parkway
Malvern, PA 19355

Date Prepared: March 12, 2014

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR § 807.92.

1. **General Information:**

Importer / Distributor:
Siemens Medical Solutions, Inc.
51 Valley Stream Parkway, E-50
Malvern, PA 19355
Establishment Registration Number: 2240869

Location of Manufacturing Site:
Siemens AG
Medical Solutions
X-Ray Products
Henkestrasse 127
DE-91052 Erlangen
Establishment Registration Number: 3002808157

Manufacturer:
Siemens Shanghai Medical Equipment Ltd.
278 Zhou Zhu Road, Shanghai
201318, China
Headquarters:
Siemens AG
Wittelsbacherplatz 2
D-80333 Munich 2, Germany
Establishment Registration Number: 3003202425

2. **Contact Person:**

Ms. Patricia D Jones
Technical Specialist, Regulatory Submissions
Siemens Medical Solutions USA, Inc.
51 Valley Stream Parkway D-02
Malvern, PA 19355
Phone: (610) 448 -3536 Fax: (610) 448-1787

Email: patricia.d.jones@siemens.com

3. **Device Name and Classification:**

Trade Name:	Multix Select DR
Classification Name:	Stationary X-Ray System
Classification Panel:	Radiology
Classification Regulation:	21 CFR §892.1680
Device Class:	Class II
Product Code:	90 KPR

4. **Legally Marketed Predicate Device**

Trade Name:	Multix Fusion
510(k) #:	K121513
Clearance Date:	August 10, 2012
Classification Name:	Stationary X-Ray System
Classification Panel:	Radiology
CFR Section:	21 CFR §892.1680
Device Class:	Class II
Product Code:	90 KPR

Device Description:
Multix Select DR is a product sharing same image system platform with Siemens' Multix Fusion x-ray system cleared under Premarket Notification K121513 on 08/10/2012, but target to low end DR market segment. The Multix Select DR system consists of radiologic table, x-ray generator, x-ray tube, flat panel detector (mobile (wired)), imaging system and Bucky-wall stand.

The Multix Select DR offers the following system configurations:

- A digital radiography system with a mobile (wired) flat panel detector;

The key components are a Patient Table and a Bucky wall stand which are available in different configurations. The x-ray tube is a Single Tank Tube Assembly and mounted in a column integrated on the patient table. A manual movement of the x-ray tube is available.

Similar to the cleared Multix Fusion x-ray system, Multix Select DR has the same or similar comparable components. It does not affect the indication for use nor the intended use of the device nor does it alter its fundamental scientific technology.

5. **Indication for Use:**
The Multix Select DR is a digital system used for making X-ray exposures of the head, spinal column, abdomen, thorax (lungs), internal organs and extremities with/without using conventional film/screen and CR -systems, and may be used on pediatric, adult and bariatric patients. The Multix Select DR system is not meant for mammography.

6. **Substantial Equivalence:**
The Multix Select DR is substantially equivalent to the commercially available Siemens Multix Fusion (K121513) radiographic x-ray system with similar indication for use. The Multix Fusion was described in premarket notification K121513 which received FDA Clearance on August 10, 2013. (See **Table 1** below).

Table 1: Predicate Device Comparable Properties

Predicate Device Name & Manufacturer	510(k) Number	Clearance Date	Comparable Properties
Multix Fusion SSME	K121513	08/10/2012	Indications for use X-ray tube Collimator Table X-ray Generator Bucky wall stand Digital Imaging system Flat panel detector

7. **Summary of Technological Characteristics of the Subject Device as Compared with the Predicate Device:**
The Multix Select DR uses the same Digital Imaging system as the predicate device. The differences in the Subject Device, such as Generator, X-ray Tube, Collimator, radiological table and Bucky Wall Stand, do not affect the safety or effectiveness of the device The Multix Select DR uses a flat panel detector similar to the predicate device, the difference does not affect the safety or effectiveness, which is supported by conforming to detector characteristics described per the FDA Guidance for Submission of 510(k)'s for Solid State X-ray Imaging Devices, (issued on Augus 6, 1999).

Table 2 Subject and Predicate Device Technical Properties

Comparable Properties	Subject Device Multix Select DR	Predicate Device Multix Fusion
Indications for use	The Multix Select DR is a digital system used for making X-ray exposures of the head, spinal column, abdomen, thorax (lungs), internal organs and extremities with/without using conventional film/screen and CR -systems, and may be used on pediatric, adult and bariatric patients. The Multix Select DR system is not meant for mammography.	The Multix Fusion system is a radiographic system used in hospitals, clinics, and medical practices. Multix Fusion enables radiographic exposures of the whole body including: skull, chest, abdomen, and extremities and may be used on pediatric, adult and bariatric patients. Exposures may be taken with the patient sitting, standing, or in the prone position. The Multix Fusion system is not meant for mammography. The Multix Fusion uses a mobile

Comparable Properties	Subject Device Multix Select DR	Predicate Device Multix Fusion
		(wired) for generating diagnostic images by converting x-rays into image signals. The Multix Fusion is also designed to be used with conventional film/screen or Computed Radiography (CR) cassettes.
X-ray tube	OPTIPHOS 135/30/55R	OPTITOP 150/40/80HC-100
Collimator	Manual	Manual or automatic* (ACSS)
Table	Floating table top	Lifting and floating table top
X-ray Generator	55 kW	55 kW/ 65 kW/ 80 kW
Bucky wall stand	Manual vertical movable Bucky Wall stand, Non-tiltable Bucky Tray.	Manual vertical movable Bucky Wall stand, tiltable Bucky Tray.
Digital Imaging system	Fluorospot Compact High - Res Digital Imaging	Fluorospot Compact High - Res Digital Imaging
Flat panel detector	DRZ+ (Gadox) with amorphous silicon (a-Si) technology	Cesium iodide scintillator (CsI) with amorphous silicon (a-Si) technology

The modifications included in the comparison table above (see **Table 2**) and described throughout this submission do not alter the Indications for use or fundamental scientific technology of the legally marketed predicate device. The differences between the legally marketed predicate device and the subject device have been assessed via Verification and Validation as well as Risk Management. Any differences in technological characteristics are accompanied by information within this submission that demonstrates the device is as safe and effective as the predicate device and do not raise different questions of safety and effectiveness than the predicate.

8. **Performance Testing**

Siemens claims conformance to a signed statements of performance standards and Federal X-ray Performance Standards. This submission contains performance data to demonstrate continued conformance with special controls for medical devices containing software for a Moderate Level of Concern software per FDA's Guidance Document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" issued on May 11, 2005.

Detector of the Subject Device conforms to the guidance for the submission of 510(k) for Solid State X-ray Imaging Devices. Non-clinical Data is provided in Original 510k submission Appendix G.

Testing for verification and validation of the device was found acceptable to support the claims of substantial equivalence.

EMC Mechanical Safety electrical safety was evaluated according to the IEC Standards. Siemens certify to conformance Voluntary Standards Covering Electrical and Mechanical Safety." (See **Table 3** below). In conclusion, the identified risk of EMC/Mechanical/Electrical hazards was mitigated and is substantially equivalent to the predicate device in terms of safety and effectiveness.

Siemens conforms to Voluntary and EPCR standard (see **Table 3** below).
Siemens hereby certifies that the subject device the Multix Select DR will be in compliance with the following recognized consensus standards covering electrical and mechanical safety listed in **Table 3** below.

Table 3: Conformance to Voluntary Standards

Recognition Number	Product Area	Title of Standard	Refer. No.& Date	Standards Dev. Org.
5-4	General	Medical Electrical Equipment - Part 1: General Requirements for Safety, 1988; Amendment 1, 1991-11, Amendment 2, 1995	60601-1	IEC
5-27	General	Medical Electrical Equipment - Part 1: General Requirements for Safety Collateral Standard: Safety requirements for medical electrical system	60601-1-1: 2000	IEC
5-34	General	Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral standard: Electromagnetic Compatibility - Requirements and Tests (Edition 2:2001 with Amendment 1:2004; Edition 2.1 (Edition 2:2001 consolidated with Amendment 1:2004)	60601-1-2	IEC
12-199	General	Medical Electrical Equipment - Part 1: General requirements for basic safety3.Collateral Standard: General requirements for Radiation protection in diagnostic X-ray equipment.	60601-1-3:First Ed. 1994-07	IEC
12-210	Radiology	Medical Electrical Equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment	60601-1-3:Ed. 2.0 2008-01	IEC
5-41	General	Medical Electrical Equipment - Part 1-4: General requirements for safety -- Collateral standard: Programmable electrical medical systems, edition 1.1	60601-1-4:2000 Consol. Ed. 1.1	IEC
5-40	General	Medical devices - application of risk management to medical devices	14971 Second edition 2007-	ISO

Recognition Number	Product Area	Title of Standard	Refer. No.& Date	Standards Dev. Org.
			03-01	
13-8	Software	Medical device software - Software life cycle processes	62304 Ed. 1.0	IEC
2-156	Biocompatibility	Biological evaluation of medical devices -- part 1: evaluation and testing	10993-1:2009	AAMI ANSI ISO
12-34	Radiology	Medical electrical equipment - Part 2-7: Particular requirements for the safety of high-voltage generators of diagnostic X-ray generators	60601-2-7 (1998)	IEC
12-126	Radiology	Medical electrical equipment - Part 2: Particular requirements for the safety of X-ray source assemblies and X-ray tube assemblies for medical diagnosis	60601-2-28: 2010	IEC
12-127	Radiology	Medical Electrical Equipment - Part 2: Particular requirements for the safety of associated equipment of X-ray equipment	60601-2-32: 1994	IEC
12-238	Radiology	Digital Imaging and Communications in Medicine	PS 3.1-3.20 (2011)	NEMA
N/A	Radiology	Medical Electrical Equipment - Part 1-6: General requirements for safety -- Collateral standard: Usability ,First edition, 2004	60601-1-6 (2004)	IEC
12-201	Radiology	Medical electrical equipment - Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy	IEC 60601-2-54 (Edition 1.0)	IEC

Siemens hereby certifies that the subject device the Multix Select DR will meet the applicable requirements of the FDA Performance Standards for Ionizing Radiation Emitting Products for diagnostic X-Ray systems and their major components, as listed below, prior to introduction into interstate commerce. All data will be available for inspection at the firm.

Table 3 (cont.): Required Performance Standards

21 CFR Title No.	Title of 21CFR Section
1020.30(c)	Manufacturer's Responsibility (Certification)
1020.30(e)	Identification of X-ray components
1020.30(g)	Information to be provided to assemblers
1020.30(h)	Information to be provided to users

21 CFR Title No.	Title of 21CFR Section
1020.30(j)	Warning label
1020.30(k)	Leakage Radiation
1020.30(l)	Radiation from components other than the diagnostic source assembly
1020.30(m)	Beam Quality
1020.30(n)	Aluminum equivalent of material between patient and image receptor
1020.31(a)	Control and indication of technique factors
1020.31(b)	Reproducibility
1020.31(c)	Linearity
1020.31(d)	Field limitation and alignment for mobile, portable and stationary general-purpose x-ray systems
1020.31(e)	Field indication and alignment on stationary general purpose x-ray equipment
1020.31(j)	Beam-on indicators

9. **General Safety and Effectiveness Concerns:**
Instructions for use are included within the device labeling, and the information provided will enable the user to operate the device in a safe and effective manner. Several safety features including visual and audible warnings are incorporated into the system design. In addition the Multix Select DR is continually monitored, and if an error occurs, the system functions will be blocked and an error message will be displayed.

Furthermore the operators are health care professionals familiar with and responsible for the evaluating and post processing of X-ray examinations to be performed. To minimize electrical, mechanical and radiation hazards, Siemens adheres to recognized and established industry practice, and all equipment is subject to final performance testing.

10. **Conclusion as to Substantial Equivalence:**
The Multix Select DR is intended for the same clinical use as Multix Fusion, and it uses the same or similar components as cleared in Multix Fusion.

The functionality of Multix Select DR is similar to the predicate device. It is Siemens opinion, that the Multix Select DR is substantially equivalent to the cleared predicate device the Multix Fusion (K121513) radiographic x-ray system.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 10, 2014

Siemens Medical Solutions, Inc.
% Ms. Patricia Jones
Technical Specialist, Regulatory Submissions
51 Valley Stream Parkway
MALVERN PA 19355

Re: K132934
Trade/Device Name: Multix Select DR
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: KPR
Dated: March 12, 2014
Received: March 13, 2014

Dear Ms. Jones:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K132934

Device Name
Multix Select DR

Indications for Use *(Describe)*

The Multix Select DR is a digital system used for making X-ray exposures of the head, spinal column, abdomen, thorax (lungs), internal organs and extremities with/without using conventional film/screen and CR -systems, and may be used on pediatric, adult and bariatric patients. The Multix Select DR system is not meant for mammography.

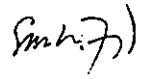
Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*



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